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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,271	07/31/2003	Michael P. Whitman	H-PM-00021 (1800-21)	5470
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Tyco Healthcare Group LP 60 Middletown Avenue North Haven, CT 06473			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,271	Applicant(s) WHITMAN ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,15-20,28-33,39,40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,15-20,28-33,39,40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim Rejections - 35 USC § 103

2. Claims 11, 12, 15, 16, 19, 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (US 6,673,058).
3. Snow discloses an orifice introducer device comprising: a tubular member (10) having a lumen and a distal end; a distal portion (see Fig. 7b) having a proximal end detachably connected to the tubular member, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end (42) of the distal portion contracts from a radially outward position to a radially inward position such that the proximal portion has to have a smaller diameter than a diameter of the tubular member (C8:L22-24). Claim 12: when the distal portion is secured to the distal end of the tubular member, a distal end of the distal portion has a smaller diameter than the diameter of the tubular member (see Fig. 7b). Claim 15: further comprising a tubular insertion device within the lumen of the tubular member (C9:L17-25). Claim 16: the tubular insertion device is configured to detach the distal portion from the tubular

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member (C9: L17-25). Claim 45: the proximal end of the distal portion contracts from the radially outward position to the radially inward position via flexure of the distal portion (C8:L22-24). Claim 46: the proximal end is biased toward the radially inward position when the proximal end is in the radially outward position (C8:L22-24).

4. Snow does not disclose that the proximal end having an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction. However Snow teaches another embodiment having grooves (Figs. 6c-6g) in order to secure a strong friction fit. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate protuberance on the embodiment of Fig. 7b to also ensure a secure fit during use. The contact between the distal end of the tubular member and a side of the annular groove is maintained by the force applied by the dissolvable portion of the distal tip which also constrains the proximal end against radial contraction.

5. Regarding claim 19, It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute elastomeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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6. Claims 11, 12, 15-19, 28, 31-33 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127) in view of Michels (US 6,332,877).

7. Dormia discloses an introducer (Fig. 3, 6, 8) comprising a tubular member (1) having a lumen and a distal end (14, 6); a distal portion (9) having a proximal end (for example 16, Fig. 8) detachably connected (as in joined) to the tubular member (for example as seen in right side of Fig. 8), wherein when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts from a radially outward position to a radially inward position such that the proximal portion has a smaller diameter than the tubular member (Left side of Fig. 8).

8. Dormia does not disclose that the distal portion has an annular groove that receives the distal end of the tubular member such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction. However, Michels discloses an insertion tube with a detachably connected tip. Michels discloses many different configurations for the distal portion (see Figs 5-8), particularly one configuration (Fig. 6) such that the tip has an annular groove that receives the distal end of the tubular member (14) and having a distal skirt (28) that surrounds the outer surface of the tube. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the cap with the outer skirt (Fig. 6) with a cap that just contacts the distal surface of the tube (Fig. 8 of Michels and Fig. 8 of Dormia) since the two structures are well known equivalents in the art at the time of the invention. Because the two distal portion caps were art recognized equivalents at the time of the invention was made, one of ordinary

skill in the art would have found it obvious to make the substitution, since substitution of one known element for another would have yielded predictable results, namely a secure connection between the distal portion and the tubular member. Adding the skirt to the distal portion of the Dormia invention will provide a more secure attachment and prevent slippage due to user error during use. The distal skirt will constrain the proximal end of the distal portion against radial contraction. The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a flexible shaft.

Claim 2 and 40: The distal end (19) of the distal portion has a smaller diameter than a diameter of the tubular member, when secured to the distal end of the tubular member (Figs. 3 and 6). Claim 15: A tubular insertion device (10) is inserted through the lumen of the tubular member. Claim 16: The tubular insertion device is configured to detach the distal portion from the tubular member when inserted through the tubular member (capable of). Claim 17: A recovery device (7) for withdrawing the distal portion through the tubular member when the distal portion has been detached from the tubular member. Claim 28: Dormia further discloses a method of using the device that includes detachably securing a proximal end of a distal portion to the distal end of the tubular member (as seen in Fig. 6 and in combination with the features taught by Michels above); inserting the distal end into an orifice (Col 4, line 43), selectively detaching the distal portion [(Col 4, line 57-60) and (Fig. 6)], the distal portion

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contracting to have a diameter smaller than the tubular member (compare right and left side of Fig. 8) and withdrawing the distal portion through the tubular member (Col 4, Lines 57-60). Claim 33: the step of selective detaching (in other words, selecting to detach or selecting to not detach the distal tip) includes inserting a tubular insertion device (10) for contacting the inner wall of the distal portion (18) (Fig. 1) (selecting to detach or not is determined by how far the insertion device is inserted through the tubular member). Claims 42 and 43: the distal tip is conical and tapered. Claim 45: the proximal end of the distal portion contracts from the radially outward position to the radially inward position via flexure of the distal portion (C4:L5-57). Claim 46: the proximal end is biased toward the radially inward position when the proximal end is in the radially outward position (C4:L55-57).

9. Regarding claim 18, Dormia fails to disclose that the recovery device is a string. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to replace the tubular recovery device with a string because it would reduce the overall profile of the device. Applicant has not disclosed that the string provides an advantage, is used for a particular purpose or solves a stated problem. In fact, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the introducer. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

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10. Regarding claim 19, It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute elastomeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

11. Claims 20 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dormia (US 5,176,127) in view of Puskas (US 6,042,538).

12. Dormia discloses all the limitations of the invention substantially as claimed as stated above except for the surgical stapler. Dormia does disclose the insertion of electrically operated surgical appliances such as electrically driven scalpels.

13. Puskas discloses inserting instruments into an endoscope that include retractors, staplers, suction devices, and electric devices.

14. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a surgical stapler into the invention of Dormia in the place of an electrical scalpel since the two surgical devices were art recognized equivalents at the time of the invention was made. Additionally, it is well known in the art to use endoscopes as a guiding in device for surgical staplers.

Response to Arguments

15. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELIZABETH HOUSTON** whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

1/18/10